# PSJ3 Exhibit 180

## **CDC Guidelines Potential Impact**



## **Agenda**

Brief Summary of Related Analyses and Research Findings

Current work and plan forward



### **CDC Guidelines Impact**

- Part of a multi-year continuum of related events
  - Guidelines and other rules already in place in many states
  - HCP's commonly bring up state board, DEA and other pressures unprompted in market research setting and cite as a reason for reduced opioid / ERO prescribing
  - Some payers have implemented guidelines (e.g., BCBS has a PA on all opioids, though impact was limited)
  - Media and national / state politics adding to the existing climate
- Any impact is most likely to occur on adoption / implementation, not issuance
  - Adoption could vary (timing, mandated vs optional, modification, etc.)



## 26 different legislative, regulatory, of guidance events analyzed (2011 – present)

- Measurable impact only when required action is mandated.
- > Strictness of rules and extent of enforcement are factors

#### Impact of All Strengths

#### WA (Jan 2012)

Refer to pain specialist for non-cancer pain at >= 120 mg MME/day. PCP can exempt out with CME

	ERO		OxyContin			
	2011	2012	2011/2012 Growth	2011	2012	2011/2012 Growth
WA State	643K	608K	-5.4%	149K	131K	-11.9%
Rest of Nation	22.6M	22.1M	-2.2%	5.6M	5.1M	-9.1%

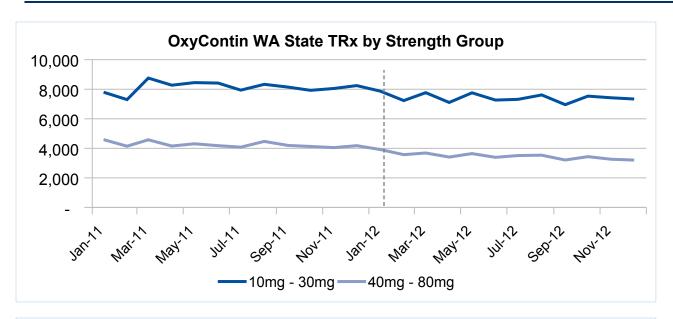
#### **OH (May 2013)**

Chronic, non-terminal pain guidelines including a "pause" at >= 80 mg MME/day

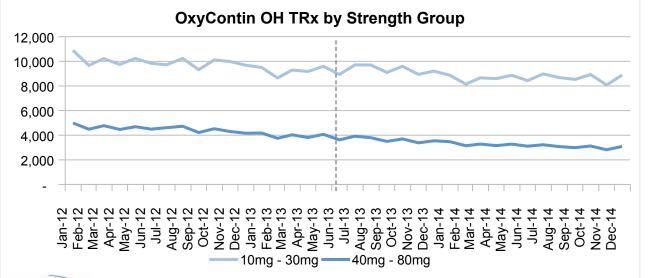
	ERO			OxyContin		
	12 mos (Apr 13)	12 mos (Apr 14)	12/12 Growth	12 mos (Apr 13)	12 mos (Apr 14)	12/12 Growth
OH State	902K	834K	-7.6%	1351	X 130K	-3.5%
Rest of Nation	21.7M	21.4M	-1.3%	22.4N	1 22.1M	-1.6%



## When there is a mg Morphine Equivalent Per Day Cutoff or Requirement, Stronger Declines in Higher Strengths Can Be Expected



12/12 Growth End Dec 2012				
	Rest of			
	WA State	Nation		
10-30mg	-9%	-6%		
40-80mg	-18%	-13%		



12/12 Growth End May 2014				
	Rest of			
	OH State	Nation		
10-30mg	-5%	-1%		
40-80mg	-17%	-10%		



# Past and continuing market research helps evaluate the impact of state guidelines and other regulations with HCP's and Payers

HCP's generally agree that treatment of chronic pain is changing, especially among those aware of changing guidelines and regulations

Factor	Most Impacted	How HCP's Are Responding		
State Legislation  State Board / DEA pressure (enforcement)	PCP's	<ul> <li>Fewer opioid Rx's; fewer tablets per Rx</li> <li>Alternative therapies considered first (e.g., physical therapy, accupuncture, NSAID's, gabapentin, Lyrica, etc.)</li> <li>ERO is becoming a last resort</li> <li>More background checking</li> <li>Referrals to pain specialists</li> </ul>		
Payer Pressure	Pain Specialists	<ul> <li>Fewer opioid Rx's; fewer tablets per Rx</li> <li>Decreasing brand utilization</li> <li>Increased utilization of generic non-opioids</li> </ul>		



#### **Current Work and Plan Forward**

- 2 Phase IMS Longitudinal Patient Analysis to Help Determine Potential Impact
  - National level maximum impact on patients & Rx's for all opioids, ERO's and Purdue based on current guidelines
    - Results expected by March 10
  - Detailed state level data with flexibility to adjust parameters (e.g. levels of MME/day)
    - Results expected mid-April
- Stakeholder research (e.g., HCP, Payer) to determine potential impact and help identify opportunities
  - o multi-disciplinary project
  - Results expected mid-April

